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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,392	08/21/2002	Kotoku Kurachi	UM-06855	7886

7590 08/09/2007

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EXAMINER	
NGUYEN, QUANG	

ART UNIT	PAPER NUMBER
1633	

MAIL DATE	DELIVERY MODE
08/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/018,392	KURACHI ET AL.	
	Examiner	Art Unit	
	Quang Nguyen, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *19 and 20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/25/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment filed on 4/30/07 was entered.

Claims1-21 are pending in the present application. Claims 19-20 were withdrawn previously because they are directed to a non-elected invention.

Applicant's election with traverse of the following species in the reply filed on 1/25/07 is acknowledged. The elected species are: (a SEQ ID NO:144 as a portion of SEQ ID NO: 93; (b) Factor IX as a species of an encoded protein; (c) Human Factor IX promoter as a species of a promoter; and (d) mammalian host as a species of a host cell.

The traversal is on the ground(s) that: (a) SEQ ID NOS:91 and 94-144 are physically and chemically within the same class, and that these nucleic acid portions all contain significant overlapping segments of identical nucleotide sequence; and therefore it would not be undue burden for the examiner to search and examine all of the SEQ ID NOs.; (b) Similarly, all recited encoded proteins are physically and chemically within the same class; all recited promoters are physically and chemically within the same class; and all recited host cells are also within the same art-recognized class.

They are not found persuasive because the searches and examination for all of **52 different SEQ ID Nos**. in addition to the previously examined SEQ ID NO:3 are undue burden for the examiner. Similarly, the searches and examination for **all 14 distinct encoded proteins** and **all 18 distinct promoters** recited in the claims would

also undue burden to the examiner. Please also note that the search is not necessarily limited only to the patent database, but also includes non-patent literature databases.

The requirement is still deemed proper and is therefore made FINAL.

In light of the nature of the invention, the Examiner examined SEQ ID NO:144 (the elected species) together with SEQ ID NO:91 (contained within SEQ ID NO:144) and SEQ ID NO:93 (a portion of SEQ ID NO:3 previously examined).

Accordingly, claims 1-18 and 21 are examined on the merits herein with the aforementioned SEQ ID Nos. and the above elected species for the encoded protein and the promoter.

Response to Amendment

The rejection under 35 U.S.C. 112, first paragraph, for the lack of Written Description was withdrawn in light of Applicant's amendment.

The rejection under 35 U.S.C. 102(e) as being anticipated by Stafford et al. (US 6,531,298) was withdrawn in light of Applicant's amendment and in favor of stronger rejections applied below.

The rejection under 35 U.S.C. 102(b) as being anticipated by Clark, A.J (WO 95/3000) was withdrawn in light of Applicant's amendment and in favor of stronger rejections applied below.

Priority

If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 120, a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be included in the first sentence(s) of the specification following the title or in an application data sheet. **For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications**.

It is noted that in the Amendment filed on 1/23/06, Applicants still did not indicate the relationship between the present application with the US Application No. 09/328,925, filed on 06/09/1999, now US patent 6,610,900.

Claim Objections

Claims 1-2 are objected to because of the phrase "said age regulatory sequences consists of" is not grammatically correct. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 13-16 are rejected under 35 U.S.C. 101 because the claims encompass a non-statutory subject matter. ***This is a new ground of rejection necessitated by Applicant's amendment that results in the rejoinder of Groups II-III.***

Claims 13-17 are drawn to a host cell containing the recombinant expression vector of the present invention. Since the term a "host cell" as defined by the specification at page 56, lines 1-11) encompasses a fertilized egg cell, or a cell capable of generating a multicellular organism, and is present or intended to be present in a living animal, including a human, said host cell becoming integrated into the human being and therefore being an inseparable part of the human being, which is a non-statutory subject matter. See 1077 O.G. 24, April 21, 1987.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Amended claims 1-2, 4-5, 7-18 and 21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

1. A recombinant expression vector comprising in operable combination i) a nucleic acid sequence of interest, ii) a promoter sequence and iii) one or more age regulatory sequences selected from SEQ ID NO:3 and a nucleic acid sequence comprising SEQ ID NO: 91, wherein the age regulatory sequences are located 3' of said nucleic acid sequence of interest;

2. An isolated host cell or a non-human host cell containing the same recombinant expression vector; and

3. A method of expressing a nucleic acid sequence of interest into a cell, comprising:

a) providing: i) a cell, ii) a nucleic acid sequence of interest, iii) a promoter sequence, and iv) one or more age regulatory sequences selected from SEQ ID NO: 3 and a nucleic acid sequence comprising SEQ ID NO: 91,

b) operably linking said nucleic acid sequence of interest, said promoter sequence and said one or more age regulatory sequences, wherein the age regulatory sequences are located 3' of said nucleic acid sequence of interest to produce a transgene; and

c) introducing said transgene into said cell to create a treated cell under conditions such that said nucleic acid sequence of interest is expressed in said treated cell;

does not reasonably provide enablement for other recombinant expression vector containing any other portions of SEQ ID NO:3 or SEQ ID NO:93 as an age-regulatory sequence or in any other operable combinations, or any other host cells containing the same. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. ***This is a modified rejection necessitated by Applicant's amendment that results in the rejoinder of Groups II-III.***

The factors to be considered in the determination of an enabling disclosure have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the state of the prior art, the relative skill of those in the art, the

predictability or unpredictability of the art and the breadth of the claims. *Ex parte Forman*, (230 USPQ 546 (Bd Pat. Appl & Unt, 1986); *In re Wands*, 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)).

The present specification is not enabled for the instant broadly claimed invention for the reasons discussed below.

(a) The breadth of the claims

Claims 1-2, 4-5 and 21 encompass a recombinant expression vector comprising **in any operable combination** i) any nucleic acid sequence of interest, ii) any promoter sequence and iii) one or more age regulatory sequences selected from SEQ ID NO:93 or any portion of SEQ ID NO:93 comprising the sequence of SEQ ID NO:91; a method for expressing any nucleic acid sequence of interest in an isolated cell by introducing into the cell the same expression construct; and the resulting treated and isolated cell.

Claims 7-18 encompass a recombinant expression vector comprising **in any operable combination** i) any nucleic acid sequence of interest, ii) any promoter sequence and iii) an age-related regulatory sequence selected from SEQ ID NO:93 and **any portion of SEQ ID NO:93, not necessarily limited to a portion comprising the sequence of SEQ ID NO:91 (e.g., including any fragment from 5 contiguous nucleotide residues of SEQ ID NO:93)**; a method for expressing any nucleic acid sequence of interest in any cell (both *in vitro* and *in vivo*) by introducing into the cell the same recombinant expression vector; and **any host cell (both *in vitro* and *in vivo*) containing the same recombinant expression vector**.

(b) The state and the unpredictability of the art

At about the filing date of the present application (6/6/2000), little was known about any age-related regulatory activity of SEQ ID NO:3, let alone for any portion thereof as evidenced by the teachings of Kurachi et al. (Science 285:739-743, 1999); Kurachi et al. (Arteroscler. Thromb. Vasc. Biol. 20:902-906, 2000) and Zhang et al. (J. Biol. Chem. 277:4532-4540, 2002). Kurachi et al. (Science 285:739-743, 1999) state "[w]e have identified another unique structure in the 3' UTR, AE3', which is responsible for the 3' UTR's critical function in age regulation of hFIX gene. This function of AE3' presumably is due to the sl structure-forming dinucleotide repeats that are present in the 3' UTR" (page 743, first column, first paragraph). Even in 2002, Zhang et al still state "the age-related increase of circulatory hPC in the animals carrying –1462hPCm1/AIE was accompanied by a similar age-related increase pattern in the liver mRNA level (Fig. 6G), suggesting that AIE function to induce age-associated elevation of mRNA levels, most likely through increasing mRNA stability. The underlying molecular mechanisms remain to be elucidated." (page 4538, second column, second full paragraph). Additionally, the physiological art is recognized as unpredictable (MPEP 2164.03), particularly for age-related regulatory activity *in vivo* in the present invention.

(c) The amount of direction or guidance presented

Apart from the exemplification showing that the entire SEQ ID NO:3 (AE') and at best the 102-nucleotide nucleic acid stem-loop forming sequence of SEQ ID NO:91 within both SEQ ID NO:3 and SEQ ID NO:93 (AE3") are capable of conferring an age-associated stable gene expression pattern, the instant specification fails to provide sufficient guidance for a skilled artisan on **how to make and/or use any other age-**

regulatory sequence fragments or portions of SEQ ID NO:3 and/or SEQ ID NO:93 that do not comprise at least the 102-nucleotide nucleic acid stem-loop forming element of SEQ ID NO:91. The instant specification also does not provide sufficient guidance for a skilled artisan on how to make and use any of the instant invention's age-regulatory sequence **in any operable combination other than the age-regulatory sequence has to be 3' of the nucleic acid sequence of interest**. Zhang et al. clearly demonstrated that AE" does not function as a transcriptional enhancer to confer its age-associated stable gene expression pattern (page 4538, second column, second full paragraph). Thus, given the lack of sufficient guidance provided by the present application, it would have required undue experimentation for a skilled artisan to make and use the recombinant expression vector, a host cell and the methods as as broadly claimed.

As set forth in *In re Fisher*, 166 USPQ 18 (CCPA 1970), compliance with 35 USC 112, first paragraph requires:

> That scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the are; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved.

Accordingly, due to the lack of sufficient guidance provided by the specification regarding to the issues discussed above, the unpredictability of the physiological art in general, and the breadth of the instant claims, it would have required undue

experimentation for one skilled in the art to make and use the instant broadly claimed invention.

The examiner notes that in the Amendment filed on 1/23/06 (pages 8-9); Applicants failed to address the issue of the recited vector components in any operable orientation or combination as set forth in the Office action mailed on 10/20/05 (pages 6-11).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. ***This is a new ground of rejection necessitated by Applicant's amendment that results in the rejoinder of Groups II-III.***

Claims 4 and 5 recite the limitation "The nucleic acid sequence of claim 1" in line 1 of the claims. It is unclear what is encompassed by this limitation. Which nucleic acid sequence? Do Applicants refer to the recombinant expression vector of claim 1 or the nucleic acid sequence of interest or the promoter sequence or one of the age regulatory sequences? Clarification is requested because the metes and bounds of the claim are not clearly determined. For the purpose of a compact prosecution, the Examiner interprets the phrase to refer to the recombinant expression vector of claim 1.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-13, 16-17 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Kurachi et al. (J. Biol. Chem. 270:5276-5281, 1995) as evidenced by Yoshitake et al. (Biochemistry 24:3736-3750, 1985). ***This is a modified rejection necessitated by Applicant's amendment that results in the rejoinder of Groups II-III.***

With respect to the elected species, Kurachi et al disclose the construction of a set of three human factor IX minigene expression vectors, p-416FIXc, p-416FIXm1 and p-416FIXm2, and the p-416FIXm1 and p-416FIXm2 constructs containing a truncated intron 1 of the factor IX gene showed 7-9 fold higher expression activities than p-416FIXc that does not contain a factor IX intron 1 sequence (see abstract). All of the expression vector constructs contain the human factor IX exon VIII along with 3' flanking genomic sequences and a minimal human factor IX promoter, FIX-416/29 promoter sequence (Figure 2; and Materials and Methods section). The human factor IX exon VIII (nucleotides 30822-32757) comprises the 3' UTR having SEQ ID NO:3 (nucleotides

31,418-32,690) as evidenced by the disclosure of Yoshitake et al. (see Figure 3, Table I and the attached sequence search). Accordingly, all the expression vector constructs of Kurachi et al. contain the 3' UTR having SEQ ID NO:3 that contains a sequence consisting of SEQ ID NO:93 or SEQ ID NO:91 or SEQ ID NO: 144. Please note that that the nucleic acid sequences flanking either SEQ ID NO:93 or SEQ ID NO:91 are parts of a nucleic acid sequence of interest; and with respect to recombinant expression vector claims, the open language term "comprising" allows the incorporation of flanking sequences to either SEQ ID NO:93 or SEQ ID NO:91. Additionally, the used promoter sequence FIX-416/29 contains a sequence that is a portion of SEQ ID NO:1 (e.g., any nucleotide sequence containing at least two contiguous nucleotides of SEQ ID NO:1 would be considered to a portion thereof).

Kurachi et al further teach the transfection of HepG2 cells with the aforementioned human factor IX minigene expression vectors (page 5277, right-hand col., fourth paragraph), and the expression of factor IX in the cell cultures was assayed (Table II and Fig. 4).

Accordingly, the teachings of Kurachi et al meet all limitation of the claims as written, and therefore the reference anticipates the instant claims.

Response to Arguments

Applicant's arguments related to the above rejection in the Amendment filed on 1/23/06 (page 10) have been considered but they are respectfully not found persuasive for the following reasons.

Applicants argue basically that the amended claims specify a particular portion of SEQ ID NO:3 together with the term "consists of", and therefore the cited reference does not teach every limitation of the claims.

All of the expression vector constructs of Kurachi et al. contain the 3' UTR having SEQ ID NO:3 that contains a sequence consisting of SEQ ID NO:93 or SEQ ID NO:91 or SEQ ID NO: 144. Please note that that the nucleic acid sequences flanking either SEQ ID NO:93 or SEQ ID NO:91 are parts of a nucleic acid sequence of interest; and with respect to recombinant expression vector claims, the open language term "comprising" allows the incorporation of flanking sequences to either SEQ ID NO:93 or SEQ ID NO:91.

Accordingly, the teachings of Kurachi et al still meet all limitation of the claims as written, and therefore the reference anticipates the instant claims.

Claims 1-18 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Jallat et al. (WO 91/02056) as evidenced by Jallat et al. (US 5,814,716) and Anson et al. (EMBO J. 3(5):1053-1060, 1984). US 5,814,716 is a continuation of the US national phase application of WO 91/02056, and is provided as an English translation for the specification and drawings of WO 91/02056). ***This is a new ground of rejection necessitated by Applicant's amendment that results in the rejoinder of Groups II-III.***

Jallat et al disclose expression vectors comprising in operable linkage a promoter (e.g., a 5 kb-human factor IX gene promoter), coding sequence for human factor IX

(hFIX), and the complete 3' UTR of the hfIX gene, particular the genomic sequence comprising 8 exons and 7 introns described by Anson et al in EMBO J 3:1053, 1984 (see the entire reference, particularly Figs. 2-3; col. 3, lines 8-64; col. 4, line 20 continues to line 10 of col. 5; Examples 1-2). The vectors comprise all of exon 8 of the hfIX gene which includes the 3' UTR that differs from SEQ ID NO:3 of the present invention by three nucleotides at positions 109, 646 and 891 of SEQ ID NO:3 as evidenced by the disclosure of Anson et al. (see at least Figure 4 on page 1057). All of the three mismatches are outside of the recited SEQ ID NO: 93, SEQ ID NO: 91 and SEQ ID NO:144. Accordingly, the expression vector constructs of Jallat et al. contain the 3' UTR having a sequence that contains a sequence consisting of SEQ ID NO:93 or SEQ ID NO:91 or SEQ ID NO: 144. Please note that that the nucleic acid sequences flanking either SEQ ID NO:93 or SEQ ID NO:91 are parts of a nucleic acid sequence of interest; and with respect to recombinant expression vector claims, the open language term "comprising" allows the incorporation of flanking sequences to either SEQ ID NO:93 or SEQ ID NO:91. Additionally, the 5 kb-human factor IX gene promoter contains at least sequence that is a portion of SEQ ID NO:1 (e.g., any nucleotide sequence containing at least two contiguous nucleotides of SEQ ID NO:1 would be considered to a portion thereof).

Jallat et al also teach introducing the above vectors into fertilized mouse oocytes for the production of transgenic mice; and liver cells that express hFIX were also recovered from the transgenic mice.

Accordingly, the teachings of Jallat et al still meet all limitation of the claims as written, and therefore the reference anticipates the instant claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-11, 13, 15-17 and 21 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6-8 and 10 of copending Application No. 11/129861. ***This is a modified rejection necessitated by Applicant's amendment that results in the rejoinder of Groups II-III.***

Although the conflicting claims are not identical, they are not patentably distinct from each other.

The claims of the present application differ from the claims of the copending Application No. 11/129861 in reciting specific age regulatory sequences of SEQ ID NO:93, SEQ ID NO:91, SEQ ID NO:144 as a portion of SEQ ID NO:3 in a recombinant

expression construct, and apart from a method of introducing a transgene into an isolated cell, claims of the present application are also directed to a recombinant expression vector, a purified nucleic acid sequence and a host cell comprising the recited specific age regulatory sequences as a portion of SEQ ID NO:3. The claims of the present application can not be considered to be patentably distinct over claims 6-8 and 10 of copending Application No. 11/129861, drawn to **a method of expressing a nucleic acid sequence of interest in a selected group of mammalian cell, including a mouse embryonic stem cell, a blastomere cell, a fertilized egg cell, using an expression construct comprising one or more age regulatory sequences selected from SEQ ID NO:3 and a functional portion of SEQ ID NO:3, when the disclosed SEQ ID NO:3 contains a sequence consisting of SEQ ID NO:93 or SEQ ID NO:91 or SEQ ID NO: 144**. Please note that that the nucleic acid sequences flanking either SEQ ID NO:93 or SEQ ID NO:91 are parts of a nucleic acid sequence of interest in the claims of the present application; and with respect to recombinant expression vector claims of the present application, the open language term "comprising" allows the incorporation of flanking sequences to either SEQ ID NO:93 or SEQ ID NO:91. Accordingly, the claims of the copending Application No. 11/129861 fall within the scope of claims 1-11, 13, 15-17 and 21 of the present application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action.and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's SPE, Joseph T. Woitach, Ph.D., may be reached at (571) 272-0739.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance.

Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

QUANG NGUYEN, PH.D.
PRIMARY EXAMINER